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Docket No. 02D-0113
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Ref: Comments – Draft Guidance – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA

Dear Sir or Madam:

The following are comments are being submitted by Implant Innovations, Inc. for your consideration relative to the above referenced draft guidance.

8. Fixture to Abutment Compatibility

- The requirement to describe the performance testing conducted to determine fixture-to-abutment compatibility is too vague. Is the agency seeking data to support claims that the implant can be mated to competitors? This requirement must be more fully described.

9. Fatigue Testing in Compression and Shear

- Document recommends implant to be supported 3mm below the anticipated crestal bone level, simulating 3mm of bone resorption. We recommend implant to be supported 2mm below the anticipated crestal bone level, as the established biologic width around implants is typically 1.5-2.0mm with the crestal bone height settling to about this distance from the implant seating surface, thus 3mm may be considered too aggressive.

02D-0113 C1

- Document recommends implant to be tested in air at 20 deg. C, at 3-15 Hz frequency. We recommend implant to be tested in air at room temperature or ambient (as 20 deg. C or 68 deg F is not room temperature and needs temperature regulated test chamber), at 30 Hz frequency. There is no significant increase in temperature of test parts at 30 Hz frequency. Hence, no change in fatigue strength would be expected.

- We recommend Staircase or Up-and-Down Method of Fatigue Testing as described in 'Failure of Materials in Mechanical Design' by J. A. Collins, John Wiley & Sons, 1981. This method provides a measure of the estimated mean fatigue strength with data analyzed statistically by observing certain characteristics of the normal distribution and the binomial distribution, and then approximating one by the other. The method involves testing the first specimen at a load of (estimated mean fatigue strength + step height, both of which are based on prior data, if available). If no prior data are available, determine the starting load from experience. Continue the test at this load until the specimen either fails or runs out at the prescribed life (5 million cycles). If the first specimen fails, test second specimen at a load level one increment (step height) lower than the previous load level. If the first specimen runs out, test the second specimen at a load level one increment (step height) higher than the previous load level. The testing data collection begins when a reversal in run out or failure occurs between subsequent specimens. Continue the test sequentially until at least 15 specimens have been tested. The details regarding the recording and analysis of data are given in the reference. The analysis gives the statistical estimate of fatigue strength and also confidence limits (say 95%) for the mean fatigue strength.

<u>10. Corrosion Testing</u>

- This section requires that a corrosion testing be performed when the implant system includes dissimilar metals. There needs to be some exceptions to time-proven use of dissimilar metals, such as commercially pure titanium used with titanium alloy, or commercially pure titanium used with gold alloy, or any combination of the three stated metals; all of which have known historical use together and are expected to behave as noble metals in simulated physiological solution. It is unlike the situation such as the use of commercially pure titanium with 316L stainless steel; where 316L stainless steel might act as a sacrificial metal since it is less noble than titanium.

<u>12. Animal and Clinical Studies</u>

- On page 13, third paragraph, the document states that clinical investigation should include a controlled clinical trial to demonstrate substantial equivalence. Occasionally, there may be justification for the use of historical controls.

- On page 15, fourth bullet, it states: *standardized radiographs to quantify the ridge height and* ***width*** [emphasis added] *of the supporting bone and locate major anatomical features.* Accurate ridge width measurements cannot be obtained from standard panoramic or periapical radiographs. Width measurements can be obtained using computed axial tomography (CAT) scanner, equipment not practical for most dental practices. CAT scans expose the patient to a relatively large dose of radiation. Lastly, CAT scans are time-consuming and very expensive. To mandate width measurements in the guidance would substantially increase patient risks, decrease the likelihood of patients volunteering to participate in clinical trials, and substantially increases the costs of conducting clinical trials. Historically, standard radiographs have provided a means to estimate crestal bone levels and determine the amount of crestal bone loss. The contribution of bone width to the monitoring of dental implant function is not readily appreciated.

- On page 16 – Pocket Probing Depth - The documentt indicates probing as a required element of dental implant monitoring. As opposed to gingival health and implant mobility, probing is an invasive procedure with marginal benefit and specific risk. At each probing session bacteria are forced into the lower sulcus and the risk of promoting a sub-clinical infection increase. Further, the inter-and intra-operator variation is quite large. Devices such as the Florida Probe were developed to help calibrate the force by which the probe is inserted. In cases of periodontitis where there is a history of active pathology, probing can serve as an indicator of treatment success or failure. For dental implants, probing and implant failure have not been correlated. Implant failures are more associated with bone loss and infection, not with soft tissue health. Lastly, the time, discomfort, and costs associated with probing **at each follow-up visit** present yet another impediment for patient's volunteering to participate in clinical studies.

  If probing does become mandatory, the incidence of bleeding, *Bleeding-on-Probing*, may be useful as an indicator of declining soft tissue health or an over aggressive amount of force used to drive the probe. In any case Bleeding-on-Probing is usually monitored when pocket depth measurements are obtained.

Thank you for your time and consideration. If you have any questions concerning these comments, please feel free to contact me directly at 561-776-6819.

Sincerely,

Jacquelyn A. Hughes, RAC

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